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GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

ALLEN, MARIANNE P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,441

Applicant(s)

PALSSON ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 67-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-66 and 70-74 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4 pages.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-66 and 70-74, in the reply filed on 6/7/04 is acknowledged. The traversal is on the ground(s) that there would be no burden of search. This is not found persuasive because as burden was previously established in the prior Office action. Groups II, III, and IV are directed to different methods with different steps and goals.

The requirement is still deemed proper and is therefore made FINAL.

Claims 66-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/7/04.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The basis for the subject matter set forth in claims 12-13 and 46-47 is not seen.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-16, 23-24, and 26-33 are directed to computer readable medium or media containing a data structure and data. As written, the data structure and data do not impart functionality when employed as a computer component and as such are considered nonfunctional descriptive material. When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978). See MPEP 2106.

With respect to claim 14, the “constraint function” is considered to be an equation or data and not an executable instruction or command.

With respect to claims 17 and 25, the requirement for “commands” is considered to be directed to a program listing or text file and not directed to software or computer executable commands.

Claim Rejections - 35 USC § 112

Claims 1-66 and 70-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-33 are directed at computer readable medium or media comprising a data structure and a constraint set. It is unclear from the claim how the data structure and

constraint set are related to each other and the computer readable media. For example, is the data structure on one disk and the constraint set on another? Is the claim directed to multiple copies of a disk containing the same data structure and constraint set? Do the data structure and constraint set interact with each other or the computer? That is, were computer executable instructions intended to be claimed? Are these claims intended to be directed to data or input for a program?

Claims 2-7, 26-30, and 32-33 are confusing and do not appear to limit the computer readable medium or media of claim 1. The limitations in these claims appear to concern the value of the data in the data structure and/or how the value is determined. This does not clearly modify either the structure of the data structure nor the constraint set in claim 1. For example, it does not appear that the data structure embraced by claim 1 would differ whether the reactant identified as a product is insulin or nerve growth factor. This information would be stored in the same way and does not require a structural change.

Claims 9-13 are similarly confusing and do not appear to limit the computer readable medium or media of claim 8.

Claim 8 is confusing in further requiring a regulatory data structure. It appears that the regulatory data structure must comprise a representation of a regulatory event but it is not known what such a representation is or whether other elements are required.

With respect to claim 14, the recitation of "constraint function" is confusing as to whether this embraces an equation or data or an executable instruction or command. If an executable instruction or command was intended, it is unclear if this is a program

separate from the data structure and constraint set on the computer readable medium or media of claim 1.

Claim 19 is confusing. It is unclear how commands can be an optimization problem.

Claim 20 is confusing in reciting linear or nonlinear. This appears to embrace all of the types of optimization problems embraced by claim 19 and not further limit the claim. See also claim 54.

Claim 23 is confusing in reciting that the data structure comprises a set of linear algebraic equations. It is unclear how this represents “a plurality of reactants to a plurality of reactions” as set forth in claim 1 where each reaction comprises a reactant, a product, and a stoichiometric coefficient. Does each algebraic equation represent a single reaction? Does one algebraic equation represent the reactants and another the products? See also claim 56.

Claim 30 is confusing in reciting a “confidence rating.” The claim does not make clear what this rating refers to.

Claim 34 is confusing as the final step is determining at least one flux distribution that minimizes or maximizes an objective function. Is this at least one flux distribution the systemic property of the preamble?

Claim 34 is confusing in reciting “an objective function.” It is not known what this is.

Claim 35 is unclear as to whether this is directed to an active step to update a value in the constraint set in some manner as the method is performed. See also claims

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36-39. Is the outcome of the at least one reaction a piece of information generated by the method?

In claim 36, is the outcome of the regulatory event a piece of information generated by the method?

Claim 37 recites “in response to time.” However, there are no time elements set forth in claim 34 and as such it is not clear what is intended.

Claim 41 is directed to the method of claim 34 further comprising a regulatory data structure. The claim does not make clear where, how, or why such an element is added. The claim does not clearly set forth an additional positive, active step nor modify an existing step. As such, the claim and dependent claims 42-52 are confusing.

Likewise, claim 48 further comprises a constraint function without clearly setting forth an additional step or modifying an existing step. As such, the claim and dependent claims 49-50 and 52 are confusing.

Claim 55 recites “modifying” the data structure and/or constraint set but does not make clear what particularly is modified, how it is modified, or why it is modified.

Claim 64 further comprises providing a gene database. It is unclear how this additional element modifies the method steps of claim 34. As written, the database is not involved in step (e) the determination of at least one flux distribution.

Claims 65-66 are confusing in further comprising identifying an open reading frame. Is the open reading frame or the identified protein the systemic property of the preamble of claim 34? Is this information used in step (e) of claim 34? When do these steps occur within the method of claim 34?

Claim 71 is directed to determining at a first and second time. However, steps (a) through (e) have no limitations to time elements and this is considered to be no different than repeating the method. The specification discloses this with respect to rates of reaction and presence or absence of products and substrates in a time dependent manner. However, the claim as written does not set forth this concept.

Claim 73 is confusing in reciting "change in an environmental condition." Claim 71 does not contain any such conditions.

Applicant is entitled to only the instant filing date of 3/1/02 and not the filing dates of either provisional applications 60/272,754 (filed 3/1/01) or 60/323028 (filed 9/14/01). The invention as set forth in the present claims is not disclosed in either provisional application. Computer readable medium or media with the limitations as set forth in the claims are not disclosed. Methods with the particular steps and requirements as set forth in the claims are not disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 17-20, 23-26, 29, 32-34, 40, 53-54, 56-61, and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/46405 (10 August 2000).

WO 00/46405 discloses a metabolic genotype for an organism including stoichiometrix matrix (the data structure) that can be analyzed using flux balance analysis

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to assess effects under different metabolic constraints. The assignment of function to an open reading frame (annotation) is disclosed. The metabolic reactions set forth include regulated reactions. The constraint set is considered to be the constraints on various fluxes and environmental inputs to the metabolic network. The flux balance analysis uses linear programming to optimize. These constraints can be varied. See at least abstract, figures, claims, and pages 3 and 7-9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (Journal of Biological Chemistry, June 1999).

Edwards et al. discloses a computer readable medium comprising a data structure and data. See abstract, results, and Figures 2-3.

The particular data required by these claims is considered to be nonfunctional descriptive material. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. See MPEP 2106.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1631

5/19/04

mpa